

Executive Summary

The reporting burden on institutions was reduced in the 1999 Annual Report on Possible Research Misconduct by the elimination of questions concerning the protection of the position and reputation of respondents and whistleblowers and the imposition of sanctions on respondents. Sufficient data were collected on these topics in previous Annual Reports.

The amount of misconduct activity - receipt of an allegation or conduct of an inquiry or investigation - reported by institutions in their 1999 Annual Report on Possible Research Misconduct increased after a previous 3-year decline.

In 1999, 72 institutions reported misconduct activities. Forty-six of these institutions opened 63 new cases; the other institutions were still responding to allegations received earlier. New cases were opened by 41 higher education institutions, 4 research organizations and 1 health organization.

Institutions received 89 allegations. The number of allegations of fabrication, falsification and plagiarism increased from 1998. One bad faith allegation was reported. The 63 new cases opened by the institutions resulted in 51 inquiries and 9 investigations. Some cases were closed following a preliminary assessment of the allegations or were received too late in the year to begin an inquiry.

Of the 3,767 annual reports, for calendar year 1999, sent to institutions on January 10, 2000, about 84 percent were returned by the March 31, 2000, deadline. This was down from about 90 percent reported for the 1998 submissions.

The effort to establish an e-mail network covering all institutions that have an active assurance is progressing well. About 92 percent of the institutions have submitted e-mail addresses for their responsible official. The e-mail network enables ORI to quickly contact institutional officials individually or en masse. ORI plans to have the calendar year 2000 annual report submitted electronically.

Ninety-five percent of the responding institutions appear to have the required policy for handling allegations of scientific misconduct. Ninety-three percent of the responding institutions indicated that they have the required policies. Another 2 percent have policies on file with ORI even though they either indicated that they did not have such a policy or did not answer the pertinent question. The institutions that reported they did not have the required policy were asked to establish one and send it to ORI for review.

The results of the 1999 Annual Report survey required considerable updating of the ORI assurance database which contains the names of all institutions that have an active assurance and therefore are eligible to receive PHS research support. Six hundred and three assurances were considered delinquent, including 521 institutions that did not return their Annual Reports by the March 31 deadline and 82 institutions that voluntarily withdrew their assurances rather than

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submit the Annual Report or submit a previously requested misconduct policy. Small businesses accounted for 69 percent of the inactivated assurances; higher education accounted for 9 percent.

By the deadline 646 institutions changed their responsible official and/or their address. Four hundred and seventy officials and 218 addresses were new. Forty-two of these institutions made both changes.

The Annual Report survey continues to encounter problems with (1) the initial response rate, (2) erroneous or confusing responses regarding the availability of policies, (3) unanswered questions, and (4) ambiguous responses. ORI will address these problems through the *ORI Newsletter*, the ORI website, the cover letter accompanying the Annual Report form, and the newly organized e-mail network, including the planned electronic submission of the CY 2000 annual report.

Introduction

This report describes the conduct and results of the 1999 Annual Report on Possible Research Misconduct. It presents the regulatory basis for requiring institutions to submit the report, the report results, methodology employed, the follow-up actions taken, the problems encountered, and proposed solutions.

Requirements of Federal Regulation

The PHS regulation (42 CFR Part 50, Subpart A) on misconduct in science places several requirements on institutions receiving or applying for funds under the PHS Act that are monitored by ORI's Assurance Program.

Section 50.103(a) of the regulation states: "Each institution that applies for or receives assistance under the Act for any project or program which involves the conduct of biomedical or behavioral research must have an assurance satisfactory to the Secretary that the applicant: (1) Has established an administrative process that meets the requirements of this Subpart, for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored biomedical and behavioral research conducted at the applicant institution or sponsored by the applicant; and (2) Will comply with its own administrative process and the requirements of this Subpart."

Section 50.103(b) of the regulation states: "The institution's assurance shall be submitted to the [ORI], on a form prescribed by the Secretary. . .and updated annually thereafter. . .An institution shall submit, along with its annual assurance, such aggregate information on allegations, inquiries, and investigations as the Secretary may prescribe."

To fulfill this requirement, institutions must submit to ORI an Annual Report on Possible Research Misconduct (PHS form #6349).

In administering the Assurance Program, ORI determines whether an institution has a current assurance on file so that PHS funds may be awarded, and reviews the information submitted on the Annual Report form to see whether the institution is complying with the regulation.

Results/Methodology

This section describes the results and methodology of the 1999 Annual Report under the following headings: (1) Misconduct Activities Reported; (2) Procedural Changes; (3) Data Collection; (4) Response Rate; (5) Changes in Institutional Population; and (6) Changes in Officials/Addresses.

Misconduct Activities Reported

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In 1999, 72 institutions reported misconduct activities—the receipt of an allegation or conduct of an inquiry and/or investigation. Forty-six institutions opened 63 misconduct cases in 1999 upon receipt of new allegations, 34 institutions were continuing to process allegations made in 1998, and 8 institutions were responding to allegations made both prior to and during 1999. The level of reported misconduct activity increased after a three-year decline. See Table 1. Of the 46 institutions reporting new allegations in 1999, 41 were institutions of higher education, 4 were research organizations and 1 was a health organization.

Table 1: Number of Institutions Reporting Misconduct Activities, Number of Institutions Reporting New Allegations and Number of New Cases Opened, 1995-1999.			
Annual Report	# of Institutions Reporting Activity	# of Institutions - New Allegations	# of New Cases Opened
1999	72	46	63
1998	67	41	54
1997	73	48	64
1996	88	54	70
1995	96	61	81

In their submissions, institutions report the receipt of an allegation of scientific misconduct, the type of misconduct, and the conduct of an inquiry and/or investigation. Reportable activities are limited to alleged misconduct involving PHS-supported research, research training, or other research-related activities.

For 1999, institutions reported receiving 89 allegations. The number of allegations of fabrication, falsification and plagiarism increased from 1998. See Table 2.

Table 2: Types of Misconduct and Total Number of New Allegations Reported, 1995-1999.					
Annual Report	Fabrication	Falsification	Plagiarism	Other	Total
1999	21	37	13	18	89

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1998	15	22	10	22	69
1997	26	34	8	24	92
1996	33	34	19	41	127
1995	24	46	13	21	104

The 63 new cases opened by the institutions in 1999 resulted in 51 inquiries and 9 investigations. Some cases were closed following a preliminary assessment of the allegation or were received too late in the year to begin an inquiry that year. The number of inquiries and investigations conducted in 1999 was more than reported in 1998, but less than in any of the three annual reporting periods prior to 1998. See Table 3.

<i>Table 3: Number of Inquiries and Investigations Conducted in Response to New Allegations, 1995-1999.</i>		
Annual Report	Inquiries	Investigations
1999	51	9
1998	38	7
1997	56	19
1996	61	25
1995	70	31

The 72 institutions reporting misconduct activity conducted a total of 82 inquiries and 27 investigations in 1999. These were in response to allegations made in 1999 and before. The number of inquiries conducted by an institution ranged from zero to three. The number of investigations conducted by an institution ranged from zero to three.

Availability of Policies and Procedures

Ninety-three percent (2,949) of the responding institutions indicated that they had the required policies for handling allegations of scientific misconduct. One hundred and ninety-six institutions (6 percent) either indicated that they did not have the required policies or did not answer the question. The remaining institutions were removed from the database for various reasons. However, 91 of the institutions reporting that they did not have a policy or did not answer the question, do have a policy on file with ORI. Of these, 76 institutions were notified that they did have a policy on file and another 15 were requested to submit an updated Small Organization Statement. The 76 policies consisted of 35 institutional policies and 41 Small

Organization Statements. Policies were requested from the remaining institutions. Thirteen institutions indicated that their misconduct policies were pending.

Bad Faith Allegations

One bad faith allegation was reported by the 46 institutions that reported new misconduct activity on their 1999 Annual Report. The ORI Model Policy for Responding to Allegations of Scientific Misconduct states that “an allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.”

Data were requested on bad faith allegations because of the concern within the scientific community about such allegations, and because many institutional misconduct policies state that such acts are subject to disciplinary action.

Data Collection

On January 10, 2000, the Annual Report form was sent to 3,767 institutions, including 171 foreign institutions that had an assurance on file with ORI as of December 1, 1998. A second mailing was conducted on March 6, 2000. Table 4 shows that more than 53 percent of the forms went to small businesses; 36 percent went to organizations most likely to conduct research (codes 10, 20, 30), and the approximate 11 percent remaining went to miscellaneous organizations.

<i>Table 4: Number of 1999 Annual Report Forms Mailed by Code and Type of Institution.</i>			
Code	Type of Institution	Number	Percent
10	Higher education	825	21.9
20	Research org., institute, lab, foundation	308	8.2
30	Independent hospital	224	5.9
40	Educational org. other than higher education	25	0.7
50	Other health, human resources, environ orgs.	369	9.8
90	Other (small business)	2,016	53.5
Total		3,767	100

Response Rate

Eighty-four percent (3,164) of the Annual Reports were returned by the final deadline. The 1998 Annual Report survey resulted in a response rate of 90 percent by the March 31 deadline. Institutions returned 68 percent (2,553) of the Annual Reports by the March 1, 2000, initial

deadline. With the second mailing an additional 611 (16 percent) Annual Reports were received by March 31.

Changes in Institutional Population

As of March 31, 2000, the assurances of 603 institutions were inactivated, including those for 521 institutions that did not return their Annual Reports and 82 were removed from the ORI database for the following reasons: 24 institutions did not expect to apply for PHS funds; 9 organizations went out of business; 8 institutions merged with another; 16 institutions did not submit their misconduct policies as requested and 25 organizations were removed for a variety of other reasons. Small businesses accounted for almost 70 percent of the assurances inactivated for not returning their Annual Report or voluntarily withdrawing their assurance. See Table 5. Institutions of higher education accounted for nearly 10 percent of the assurances inactivated.

<i>Table 5: Inactivation of Assurances by Institutional Code and Type and Cause, 1999.</i>				
Code	Institutional Type	No Report Submitted	Voluntary Withdrawal	Total
10	Higher Education	55 (10.5 %)	3 (3.7 %)	58 (9.6 %)
20	Research Org., Institute, Lab, Foundation	30 (5.8 %)	2 (2.4 %)	32 (5.3 %)
30	Independent Hospital	25 (4.8 %)	1 (1.2 %)	26 (4.3 %)
40	Educational Org., Other than Higher Education	3 (0.6 %)	0 (0%)	3 (.5 %)
50	Other Health, Human Res., Environmental Org.	51 (9.8 %)	13 (15.9 %)	64 (10.6 %)
90	Other (small businesses)	357 (68.5 %)	63 (76.8 %)	420 (69.7 %)
Total		521 (100%)	82 (100%)	603 (100%)

The inactivation of 603 assurances did not produce dramatic changes in the institutional population in the ORI Assurance Database. However, there were small percentage shifts among the types of organizations that comprise the total population. Rank order by size remained the same. See Table 6.

Table 6: ORI Assurance Database by Code, Type of Institution, Number of Institutions, Percent of Total, and Percent Change from 1998.				
Code	Type of Institution	Number	Per- cent	% Change from 1997
10	Higher education	828	21.5	-2.3
20	Research org., institute, lab, foundation	309	8.0	-0.5
30	Independent hospital	226	5.9	-0.5
40	Education org. other than higher ed.	25	0.6	-0.1
50	Other health, human res., environ. org.	368	9.6	0.0
90	Other (small business)	2,096	54.4	+3.4
Total		3,852	100	

The database query for Table 6 included initial assurances processed prior to 4/1/00.

Changes in Officials/Addresses

Besides the changes in the institutional population, extensive changes were required in the name of the responsible official and the institutional address. As of March 31, 2000, 646 institutions (17 percent) submitted such changes. Four hundred and seventy officials (12 percent) and 218 addresses (6 percent) were new. Turnover rates for responsible officials were: 40 percent for small businesses; 32 percent for higher education; 11 percent for other health, human resources or environmental organizations; 8 percent for research organizations; 8 percent for independent hospitals and less than 1 percent for educational organizations other than higher education. Small businesses accounted for 82 percent of the address changes. See Table 7.

Table 7: Change in Name of Responsible Officials and Address of Institutions by Code and Type Following the 1999 Annual Report.			
Code	Type of Institution	Officials	Address

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10	Higher education	153	1
20	Research org., institute, lab, foundation	37	13
30	Independent hospital	38	8
40	Education org. other than higher education	3	3
50	Other health, human resources, environ orgs.	53	14
90	Other (small business)	186	179
Total		470*	218*

*Includes 42 institutions that submitted both types of changes.

Follow-up Actions

The follow-up actions required by the results of the 1999 Annual Report are described under the following headings: (1) Feedback to Institutions; (2) Requesting Policies and Procedures; (3) Requesting Revised Small Organization Statement; (4) Notifying Institutions That They Have Policies; (5) Checking Reporting of Investigations; and (6) Updating Assurance Database.

Feedback to Institutions

This report on the 1999 Annual Report will be posted on the ORI home page and will be available in hard copy upon request. An article will be published in the *ORI Newsletter* in September 2000.

Requesting Policies and Procedures for Review

By the deadline date 105 institutions either answered "no" or did not answer the question about whether the institution had a policy for responding to allegations of scientific misconduct, and ORI did not have their policy on file. This number is consistent with the 108 institutions that answered similarly last year. These institutions were asked to submit their policies and procedures within 30 days for review or they would become ineligible to receive PHS research funding.

Requesting Revised Small Business Statement

Fifteen institutions either answered "no" or did not answer the question about whether the institution had a policy for responding to allegations of scientific misconduct, but ORI had a Small Organization Statement on file, dated prior to 1/1/97. Because the Small Organization Statement was revised subsequent to the submission of the statement by these organizations, they were asked to submit the revised and most current Small Organization Statement.

Notifying Institutions That They Have Policies

The 91 institutions that answered “no” or did not answer the question about the availability of an institutional policy will be notified that their institution does have a policy on file with ORI. Of this number, 56 have a Small Organization Statement and 35 have a more comprehensive institutional policy. Fifteen of the institutions, however, will be required to submit an updated Small Organization Statement. This notification is intended to reduce the erroneous responses in future reports.

Checking Reporting of Investigations

The Annual Reports of all institutions that reported misconduct activity were forwarded to the Division of Investigative Oversight (DIO) to check on the reporting of investigations by those institutions. All new activity was properly reported by institutions submitting the 1999 Annual Report.

Updating Assurance Database

The Annual Report results required a major update of the ORI assurance database. By the deadline date 603 institutions had been inactivated. Changes were recorded for the four hundred and seventy institutions that changed the name of the responsible official and the 218 institutions that changed their address. Both the responsible official and the address were changed by 42 institutions.

Problems Encountered

This section describes the problems encountered during the conduct of the 1999 Annual Report survey under the following headings: (1) Response Rate; (2) Erroneous Responses; and (3) Incomplete Reports.

Response Rate

Although the institutions were alerted to the Annual Report survey by the December *ORI Newsletter* article and by the cover letter accompanying the report form which emphasized the submission deadline, only 68 percent (2,553 of 3,767) of the Annual Reports were received by the March 1 deadline. This is down from the 74 percent received by the same date last year. Another 611 Annual Reports were returned after the second mailing.

Erroneous Responses

Ninety-one institutions responded that they did not have an institutional policy for responding to allegations of scientific misconduct when their policy was, in fact, on file with ORI. As noted earlier, 76 of these institutions were notified about the existence of the policies and the other 15 institutions have been requested to submit a current Small Organization Statement.

Incomplete Reports

Although the number of incomplete responses is declining, they still represent a problem. Seventy-four institutions did not answer the question concerning the availability of an institutional policy. Fifty-four institutions which did not report any misconduct activity did not check the box indicating that they did not have any misconduct activity to report. This number increased by one from last year.

Proposed Solutions

Solutions to the problems encountered in the 1999 Annual Report are presented under the following headings: (1) Response Rate; (2) Erroneous Responses; and (3) Incomplete Reports.

Response Rate

The major area for improvement is the total response rate. The 68 percent response to the first mailing should be improved by the planned electronic submission. Over the next few years, an effort will be made to raise the initial response rate to 90 percent. Not all organizations will be capable of an electronic submission. These institutions will still have a hard copy mailed to them, however, with a 90 percent initial response rate it would eliminate the need for a second mailing to those organizations. Test runs for the electronic submission of Annual Report data, for calendar year 2000, are currently being made.

Several steps taken previously will continue to be taken to increase the initial response of the 2000 Annual Report survey. An article will be published in the December 2000 issue of the *ORI Newsletter* calling attention to the initial submission deadline and the electronic submission. Detailed instructions and answers to frequently asked questions will be posted on the ORI website. In addition, e-mail reminders will be used regarding the Annual Report due date.

Erroneous Responses

As indicated previously, institutions that reported they did not have an administrative policy for responding to allegations of scientific misconduct when they have such a policy on file with ORI will be so notified. In addition, the revised cover letter will continue to make the following points: (1) the small organization statement satisfies the requirement for policies and procedures

if the organization has 10 or fewer employees; (2) the official named on the first page of the Annual Report should be the same official who signs for the institution on the last page, or an explanation should be offered; and (3) letterhead and/or envelopes used to submit the Annual Report should bear the name of the institution for which the Annual Report is being submitted, or an explanation should be offered.

Many organizations think that filing the small organization statement makes it unnecessary to file the Annual Report. The cover letter will remind the responsible officials that the Annual Report must be filed in all cases. A cover letter will accompany a hard copy or an electronic submission.

Incomplete Reports

Incomplete reports will continue to be addressed in the revised cover letter and modified Annual Report form. The cover letter will call attention to the question on availability of an administrative policy and will point out that the small organization statement qualifies as such a policy. The official will also be reminded that he or she should sign the form, or it will be returned without being processed.

Conclusion

Once again the Annual Report has demonstrated that it is an essential mechanism for maintaining ORI's compliance and assurance programs. The results of the 1999 Annual Report identified 603 institutions that were inactivated from the assurance database and 105 institutions that may not have the required policies and procedures for handling allegations of scientific misconduct. In addition, it provided correct information on the name of the responsible official or the institutional addresses of 646 institutions. The survey also collected information on the misconduct activities under way at institutions during the year and on institutional efforts to comply with provisions of the regulation addressing bad faith allegations received and the availability of policies to deal with misconduct allegations. Finally, this Report highlights the need for follow-up actions and identifies problems in the process for which solutions are proposed. One solution being considered to facilitate the submission of the Annual Report is the electronic transmission of the form.